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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,484	02/28/2000	DEBORAH A SCHADE	MJ-729	4022

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/381,484	SCHADE ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted February 26, 2003 is acknowledged. The examiner inadvertently made a typographic error in the prior office action, reject claim 16, instead of claim 17 in the rejections under 35 U.S.C. 103.

Claim Rejections 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The claims read on breast-feeding premature infant. Crozier G.L. et al. discloses that breast milk containing sufficient amounts of DHA and ARA to help premature infant growth health. See, the English translation, page 5, the second and third paragraph. Kyle teaches that the ratio of ARA and DHA in breast milk is about 3:1. See, e.g., table 6 in column 16.

3. Claims 14-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kyle (U.S. Patent 5,374,657), in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS) and McGraw-Hill Encyclopedia of Food, Agriculture & Nutrition.

4. Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk. The ratio of ARA:DHA is about 3:1. The concentration is about 177 mg/L of ARA and 57 mg/L of DHA. See the claims and the examples in columns 13-16. It is known that breast milk would provide sufficient ARA and DHA to the infant. (Daily

intake 175 ml/kg breast milk for the infant). The amounts would fall within the scope of claimed amounts in claims 18 and 19. See, Crozier, the English translation, page 5, the second and third paragraph. Note the daily calorie of infant is known to be about 100-120 kcal/kg. See McGraw-Hill Encyclopedia of Food, Agriculture & Nutrition, page 159.

Claim Rejections 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8, 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (U.S. Patent 5,374,657) in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS).

7. Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk. The ratio of ARA:DHA is about 3:1 to 2:1. See the claims and the examples in columns 13-16. Kyle also teaches that the presence of ARA and DHA in infant food is critical for a healthy growth for infants. See, particularly, column 1, lines 29-53.

8. Kyle does do teach expressly the administration of the infant formula to preterm infants, or the particular ratio of ARA: DHA, and the particular amounts of ARA: DHA herein.

9. However, Crozier et al. teaches that the presence of ARA and DHA in food is particularly important for preterm infants to proper growth and development because they are unable to

synthesize sufficient ARA and DHA. See, particularly, the summary. Crozier et al. further teaches that breast milk would provide sufficient ARA and DHA to preterm infants.

10. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the infant formula of Kyle for feeding preterm infants.

11. A person of ordinary skill in the art would have been motivated to employ the infant formula of Kyle to preterm infants, or more specifically, add ARA and DHA to a formula specifically formulated for preterm infant, because preterm infants are known to be in need of food with sufficient amount of ARA and DHA and formula of Kyle is known to containing about the same amount of ARA and DHA as breast milk. Further, optimization of the amounts of ARA and DHA, or the formula as whole, particularly for preterm infants is considered within the skill of artisan since the criticality of ARA and DHA for preterm infant growth is known in the art. Note the claimed ratio of ARA:DHA is within the broad range claimed by Kyle. See, particularly, claim 20 in Kyle. Further, Kyle teaches broadly the usefulness of ARA and DHA for infants, and does not specifically teach whether the infant is term infants or preterm infants. Infants, as a genus, is consist of two subgenus, term infants and preterm infants. If a reference teaches a method is useful for a genus consisting of two subgenus, it would have been prima facie obvious to one of the ordinary skill in the art that the method is useful for any of the two subgenus.

Response to the Arguments

12. Applicants' remarks submitted February 26, 2003 have been fully considered, but are not persuasive for reasons discussed below.

13. Applicants argue that rejection under 35 U.S.C. 102 based on two references is improper. Note, secondary reference cited herein merely functions as dictionary for interpretating the teaching of the main reference. Therefore the rejection is proper.

14. Applicants are in error in saying that the examiner admits that Kyle's formula is not for preterm infants. Kyle never teaches that the formula disclosed therein is not suitable for preterm infant. In response to applicant's argument that Kyle does not expressly teach the formula for preterm infant, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant situation, there is no reasonable doubt that Kyle's formula cannot be used for preterm infant.

15. Applicants improperly argue that examiner asserted that the ARA/DHA ratio in human milk is about 3:1 to 2:1. What examiner stated in the prior office action is "Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk. The ratio of ARA:DHA is about 3:1 to 2:1." 3:1 to 2:1 is the ratio of Kyle's formula. Further, applicants mistakenly assert Kyle's formula is for term infant. Kyle does not disclose

that the formula is for term infant only. As discussed above, it is obvious to one of ordinary skill in the art, to add ARA/HDA to infant formula for either term infant, or preterm infant.

16. As to the particular functions herein claimed, e.g., the benefit of the claimed method and formula for preterm infant, note newly discovered function of an old and well-known composition or method would not render the old composition and method patentably distinct. The instant claims are directed to an old or obvious method or composition. The argument that such claims are not directed to the old and well known ultimate utility (feeding preterm infants) for composition, e.g., ARA and DHA enriched formula, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various functions (enhancing growth). The ultimate utility for the claimed ARA and DHA enriched formula is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

May 8, 2003